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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,307	09/18/2003	Bassil I. Dahiyat	A-67229-13	6927

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EXAMINER :

DEJONG, ERIC S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/665,307

Applicant(s)

DAHIYAT ET AL.

Examiner

Eric S. DeJong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-5 and 7-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The communication filed by applicant on 28 September 2004 comprising a Terminal Disclaimer, an Information Disclosure Statement, a response to the previous Office Action, and an amended list of claims is acknowledged. The amended list of claims is accepted and replaces all previous claims for the instant application. Claims 1-5 and 7-25 are pending in the application and are under examination. Claims 6 is canceled.

Applicants arguments, filed 28 September 2004, have been fully considered and they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Specification

To reiterate from the previous office action, the specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification

Claim Rejections - 35 USC § 101

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5 and 7-25 are rejected under 35 U.S.C. §101 because the claimed invention is not supported by a substantial and credible asserted utility or a well established utility.

This rejection is maintained and reiterated from the previous office action, mailed 24 March 2004.

Applicants argue that an assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement under 35 USC §101. The examiner does not find the argument persuasive as MPEP §2701.02 IV states that where the asserted utility is not specific or substantial, a prima facie showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. The prima facie showing must contain the following elements:

- (A) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is neither both specific and substantial nor well-established;
- (B) Support for factual findings relied upon in reaching this conclusion; and
- (C) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

The rejection made in the previous office action is proper as it met the above criteria. As stated in the previous office action "... creating a library for further screening or testing is not a substantial and a specific utility." Further, it was asserted that "(t)he complex nature of said secondary structure, even for a known single compound, is known at

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times to defy such determination. The law clearly states that a patent is granted for a new and useful product... not prophetic or expedient statements. Nor one requiring further exploratory studies." Thus, the required elements A, B, and C for a prima facie showing is present in the rejection held from the prior office action.

Applicants submit that the application is enabled by the description example 1 from the instant Specification and further submits that the claimed method finds utility in their respective fields such as those demonstrated in examples on page 4, lines 25-30, page 34, line 22 through page 35, line 12 from the instant Specification and the literature citations exhibits A through D. The Examiner disagrees with the assertion that these examples demonstrate utility and points out that further work and experimentation is required in each of the cited examples to validate and confirm which, if any, of the variant proteins generated by the *in silico* methodologies maintained their predicted properties in the "real world". Practicing the method of the claimed invention produces a library of modified proteins generated by an *in silico* means, and as such provides only a prediction of the properties of the modified proteins that are modeled. The complex nature and reliability of computational modeling results is at the heart of the issue since *in silico* modeling is not the equivalent of producing, testing and verifying the properties of a modified protein in a "real world" environment. As previously asserted, creating a library of such variant protein sequences and structures for further testing is not a substantial and specific utility.

Applicants assert that the analogy to Brenner is not analogous to the instant claims because the claims are drawn to a method of generating a secondary library, not a "library" per se nor a composition of matter. In response the Examiner points out that in practicing the claimed invention the result is the generation of a secondary library and the utility of the method is directly related to the utility of the library created. As such the analogy to Brenner is appropriate in addressing the issue utility for the library generated and the method of generating the library.

Claims 1-5 and 7-25 are also rejected under 35 USC §112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or well established utility for the reasons set forth above and in the previous office action, one of skill in the art would clearly not know how to use the claimed invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is (571) 2723-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDJ



 12/30/04
ARDIN H. MARSCHER
PRIMARY EXAMINER